



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Examining Operations

Applicant(s): Barry, *et al.*

Serial No: 09/841,413

Art Unit: 3738

Filed: April 24, 2003

Examiner: Matthews

Title: JOINT REPAIR USING MESECHYMAL STEM CELLS

Docket No.: 640100-424

Customer No.: 27162

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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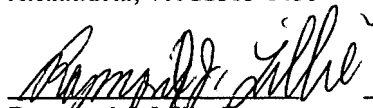
1. Reply Brief;
2. Request for Oral Hearing; and
3. A check in the amount of \$500.00; and
4. A self-addressed, postage paid, return receipt postcard, date stamp and return of which is respectfully requested.

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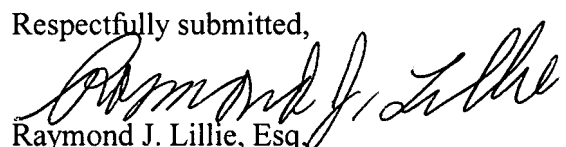
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Raymond J. Lillie, Esq. Date 6/14/07

Respectfully submitted,


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REPLY BRIEF

SIR:

This is a Reply Brief to the Examiner's Answer mailed April 19, 2007.

The Examiner has taken the position that the rejection of the Claims under 35 U.S.C. 102(e) as being anticipated by Abatangelo, et al. should be maintained because Abatangelo is a generic reference which discloses the repair of any and all connective tissue defects by administering mesenchymal stem cells in any type of carrier which is a hyaluronic acid derivative.

In effect the Examiner relies on the general disclosure of Abatangelo with respect to using (i) a combination of mesenchymal stem cells and hyaluronic acid (ii) which combination could be in the form of a solid, a liquid or a combination thereof (iii) for the treatment of any and all connective tissue defects.

Such general disclosure, however, is not an anticipation unless there is a clear and unequivocal teaching to select the claimed combination of treating a damaged meniscus with

MSCs in a liquid carrier, even though the only example that treats meniscus damage does so with a solid carrier.

It is Applicants' position that in order for Abatangelo to anticipate the claimed invention, Abatangelo must teach one skilled in the art to select from any and all connective tissue defects and any type of hyaluronic acid carrier, the specific combination of mesenchymal stem cells in an injectable liquid carrier for the treatment of damaged meniscal tissue. (See Ultradent Products Inc. v. Life-Like Cosmetics Inc., 44 U.S.P.Q. 2d 1336 (C.A.F.C. 1997), at 1342). Such teaching must be clear and unequivocal. (See In Re Arkley, 172 U.S.P.Q. 524 (C.C.P.A. 1972), at 526). Abatangelo does not provide such "clear and unequivocal" teaching as required under the patent law, and therefore Abatangelo does not anticipate the present invention. In fact, Abatangelo provides no teaching of the present invention.

The only reference to treatment of meniscus repair in Abatangelo is with reference to a solid carrier (See Ex. 7), whereby in effect Abatangelo teaches away from selecting the claimed combination. As a result, there is no basis for a position that within the four corners of Abatangelo there is the clear and unequivocal teaching to select the claimed combination. Such teaching is required for Abatangelo to anticipate.

Stated another way, when the Example of Abatangelo teaches the use of a solid carrier for meniscus repair, Abatangelo does not disclose inherently the claimed process. A general disclosure that hyaluronic acid may be used in a wide variety of forms in treating a wide variety of disorders does not disclose inherently the claimed process and does not provide a clear and unequivocal teaching to use the claimed combination for the claimed disorder.

Because the specific example does not inherently disclose the claimed invention (it uses a solid), and the general teaching does not disclose selection of the claimed combination, there is no anticipation.

In regard to Walsh, Walsh is also relevant to anticipation in that Walsh provides evidence as to why Abatangelo disclosed the use of a solid carrier when treating a damaged meniscus and why a reading of Abatangelo does not provide a clear and unequivocal teaching to select the claimed combination from the general disclosure of Abatangelo.

Abatangelo teaches specifically that, in order to repair damaged meniscal tissue, one selects a solid carrier for mesenchymal stem cells, which teaching is consistent with the conventional wisdom in the art as represented by Walsh. The Examiner's position is inconsistent with the teachings of Abatangelo and the general teachings in the art as represented by Walsh. Therefore, Abatangelo does not anticipate Applicants' claimed invention, and it is respectfully requested that the rejection under 35 U.S.C. 102(e) be reversed.

With respect to the rejection of the claims under 35 U.S. C. 102(b) as being anticipated by Goldberg, the Examiner in effect argues "inherency" based on the disclosure of Goldberg.

In regard to the Examples of Goldberg, none of the Examples of Goldberg inherently meet the claims in that none of the Examples employs a liquid carrier as claimed.

Although in the portion of the Example that appears on Pages 29 and 30, Goldberg induces osteoarthritis in a rabbit model through damage of the meniscus, the induced osteoarthritis in such model is treated by the use of a solid carrier (See Example 3). Thus, Example 3 does not meet the terms of the claims where a liquid carrier is used in that in Example 3 the rabbit model with a damaged meniscus is treated with MSCs in a solid carrier. Thus, even

if the meniscus inherently were repaired, such repair was not accomplished in accordance with the claims.

In regard to the general disclosure of Goldberg, Goldberg is directed to the repair of articular cartilage and, therefore, does not teach repair of a damaged meniscus or that such repair should be effected by use of MSCs in a liquid carrier, as claimed.

Any argument by the Examiner that when using the invention there is cartilage repair as well as meniscus repair misses the point in that Goldberg contains no teaching that if a person has meniscus damage, such damage should be repaired by use of a combination of MSCs and a liquid carrier, as claimed.

Goldberg only teaches that if there is articular cartilage damage, MSCs should be used to treat such damage. A meniscus is not articular cartilage and the Examiner does not contend otherwise.

The Examples do not inherently disclose all of the claim limitations in that the Examples use a solid carrier. Even though the treated animal has a damaged meniscus that was damaged to induce the osteoarthritis that is to be treated, meniscus repair, if any, was not produced by use of the claimed invention (MSCs in a liquid carrier).

Because there is no disclosure in Goldberg that if a meniscus is damaged, such damage should be repaired by treatment of MSCs in a liquid carrier (to the extent that the general disclosure of Goldberg discloses a liquid carrier, it is with respect to treating articular cartilage damage), Goldberg does not anticipate.

Although Goldberg teaches one skilled in the art how to repair articular cartilage, Goldberg does not teach how one skilled in the art can repair meniscal tissue. There is nothing in Goldberg which teaches that if one skilled in the art desires to repair or regenerate meniscal

tissue, one should select an injectable liquid carrier containing an effective amount of mesenchymal stem cells.

As further evidence that Goldberg does not disclose use of an injectable liquid carrier containing an effective amount of mesenchymal stem cells for repairing a damaged meniscus, Applicants note that Victor Goldberg and Arnold Caplan, two of the co-inventors of the Goldberg PCT Application, published November 19, 1998, also are co-authors of the Walsh paper, published in 1999. As noted hereinabove and in Applicants' Brief, Walsh teaches that, when repairing meniscal tissue, one needs to administer to a joint mesenchymal stem cells in a solid carrier which has a tensile strength which is sufficient to anchor the carrier in the joint. Thus, it is clear that Drs. Goldberg and Caplan did not contemplate the use of mesenchymal stem cells in a liquid suspension for repairing or regenerating meniscal tissue.

In sum, Goldberg discloses using mesenchymal stem cells to repair or regenerate articular cartilage. Goldberg does not teach repairing or regenerating meniscal tissue. Furthermore, Drs. Goldberg and Caplan, two of the co-inventors of the Goldberg PCT Application, teach, in the Walsh paper, that when one desires to repair or regenerate meniscal tissue, one needs to administer the mesenchymal stem cells in a solid implant or matrix having a sufficient tensile strength, instead of administering such cells in an injectable liquid suspension of mesenchymal stem cells. Thus, the Goldberg PCT Application is directed solely to the repair or regeneration of articular cartilage, and does not disclose generally or inherently in an example the administration of an injectable suspension of mesenchymal stem cells to repair or regenerate meniscal tissue.

Goldberg does not anticipate the claimed invention, and it is therefore respectfully requested that the rejection under 35 U.S.C. 102(b) be reversed.

For the above reasons and others, the claims on appeal are allowable over the cited references, and it is therefore respectfully requested that the rejections be reversed.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Raymond J. Lillie".

Raymond J. Lillie
Registration No. 31,778

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REQUEST FOR ORAL HEARING

SIR:

Pursuant to 37 CFR 41.47, Applicants request an oral hearing with respect to the above-identified application presently on appeal before the Board of Appeals and Interferences. The fee in the amount of \$500.00, pursuant to 37 CFR 41.20(b)(3) accompanies this request. The Assignee of the above-identified application, Osiris Therapeutics, Inc., is a small entity.

Respectfully submitted,

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